



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 210825

Product:	ERYTHROMYCIN
Lot:	210825
Expiry date:	17/12/2025
Reference:	Cumple PhEur10.5
Synonyms:	
Formula:	C ₃₇ H ₆₇ NO ₁₃
Molecular weight:	733,95 g/mol

Assay	Result	Specification	
Impurity B	0,71 %	<= 2,0 %	
Impurity A	0,21 %	<= 2,0 %	
Impurity F	<= 0,2 %	<= 1,0 %	
Impurity E	<= 0,2 %	<= 1,0 %	
Impurity D	0,43 %	<= 1,0 %	
Impurity C	2,2 %	<= 3,0 %	
Thiocyanate	0,03 %	<= 0,3 %	
Any other impurity	<= 0,2 %	<= 0,4 %	
Related substances (HPLC)	Conform	Test PhEur	
Organoleptic properties	Conform	PhEur	
Impurity L	<= 0,2 %	<= 0,4 %	
Identification	Conform (A)	Test PhEur (A)	
Impurity H	0,27 %	<= 1,0 %	
Erythromycin B	0,4 %	<= 5,0 % sps	
Residual solvent: xylene	<= 2170 ppm	<= 2170 ppm	#
Purity (A+B+C) (HPLC)	95,8 %	93,0 - 102,0 % sps	
Residual solvent: methylene chloride	<= 600 ppm	<= 600 ppm	#
Sulphated ashes	0,02 %	<= 0,2 %	
Residual solvent: acetone	<= 5000 ppm	<= 5000 ppm	#
Water	0,96 %	<= 6,5 %	
Total impurities	4,0 %	<= 7,0 %	
Elemental impurities	Conform	Test PhEur	#
Erythromycin C	2,1 %	<= 5,0 % sps	

Organoleptic characteristics: White or slightly yellow powder or colourless or slightly yellow crystals, slightly hygroscopic. Slightly soluble in water, freely soluble in ethanol (96 per cent), soluble in methanol.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 07/07/2021

Judgement:
APPROVED

Responsible: M. Mesa
Technical director: Montserrat Enrique
Manufacturer: F01003 ERCROS, S.A.
Manufacturer batch: BM575

Product	Name	Capacity	Batch
1128693	ERITROMICINA	5 g	210825-E-1
1128693	ERITROMICINA	5 g	210825-E-2
1128693	ERITROMICINA	5 g	210825-E-3
1128693	ERITROMICINA	5 g	210825-E-4
1128694	ERITROMICINA	10 g	210825-F-1
1128694	ERITROMICINA	10 g	210825-F-2
1128694	ERITROMICINA	10 g	210825-F-3
1128695	ERITROMICINA	25 g	210825-G-1
1128695	ERITROMICINA	25 g	210825-G-2
1128695	ERITROMICINA	25 g	210825-G-3
1128695	ERITROMICINA	25 g	210825-G-4
1128697	ERITROMICINA	100 g	210825-J-1
1128697	ERITROMICINA	100 g	210825-J-2
1128697	ERITROMICINA	100 g	210825-J-3
1128698	ERITROMICINA	250 g	210825-N-1
1128698	ERITROMICINA	250 g	210825-N-2
1128698	ERITROMICINA	250 g	210825-N-3
1128698	ERITROMICINA	250 g	210825-N-4
1200153	ERITROMICINA	1 kg	210825-P-1
1200153	ERITROMICINA	1 kg	210825-P-2
1200153	ERITROMICINA	1 kg	210825-P-3
1200153	ERITROMICINA	1 kg	210825-P-4
M0070092	FRASCO VIDRIO TOPACIO P-150 R/ D 51158 PP 28	150	210825

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer
(=) UE certificate

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

Date of edition: 22/05/2025

